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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,342	09/18/2000	Rudi Brands	01975.0025	8325

7590 12/03/2001

Finnegan Henderson Farabow Garrett & Dunner
1300 I Street NW
Washington, DC 20005

EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/582,342	Applicant(s) BRANDS, RUDI	
	Examin r Bao Qun Li	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): *none*.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *(See attachment)*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*.

Claim(s) objected to: *none*.

Claim(s) rejected: *1,2 and 7-25*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *11*.

10.☒ Other: *Interview Summary*

Bao Qun Li

ADVISORY ACTION

The response to the final action filed on October 31 under 37 CFR 1.116 has been entered. For purpose of appeal, the status of the claims is as follows:

Allowed claim(s): NONE.

Rejected claim (s): 1-2, 7-25.

Claim(s) objected to: NONE.

Claim Rejections - 35 USC § 102

Claims 1-2 and 9-22 are rejected under 35 U.S.C. 102 (b) over the prior art of Griffiths,s document, on the same grounds as previously stated in the Office Action mailed 08/101/2001.

Applicant argues that although Griffiths teaches all principle and every steps of the a scale-up cell culture, Griffiths does not teach that " a repeated discontinuous process" is a method in which cells are split into two populations: one portion of the produced cells of each generation cycle is used as seed cells for the next generation, while the other portion is discontinued from the propagation process and can be used for biological purpose. Therefore, Griffiths does not teach each and every element of the instant invention. The Applicant's argument is respectfully considered, however, it is not found persuasive because the ratio for splitting cells timely depends on production demand for the cell line culture. For example, if the cell need to be used for tomorrow, the cell can be split into half, whereas, if the cell need to be used three days later, the cells can be split at 1-3 ratio. The remaining cells can be considered as a continuous portion and the cells used for the end experiment of production can be considered as discontinued. Every cell culture system is repeated through the whole process. Therefore, the claimed invention is considered as a design choice rather than a patenable distinctive method unless Applicant provides an evidence to convince the significance of the 50% splitting over any other cell splitting ratio. Therefore, the rejection is till proper and maintained.

Claim Rejections - 35 USC § 103

Claims 1-2 and 7-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (Scale-up of suspension and Anchorage-dependent Animal cells in Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, pp.59-75), and Pollard (Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, Step 14-20 on

page 3 and Section 3.2 on page 4-5) on the same ground as previously stated in the office action mailed 08/01/2001.

Applicant argues that even Griffiths teaches all principle and every element of large-scale-up cell culture and Pollard does disclose the cell can be harvested and frozen. The examiner has failed to demonstrate that one skilled in the art would be motivated to combine the Griffiths and Pollard reference. The combined references did not provide all of the elements of the instant invention, the examiner has not shown that the references contain any language regarding the desirable of the combining the references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge for cells spliting in certain ration according to the demanded for the use the freezing cell to maintain the future demand as told by Griffiths and Pollard is generally available to one of ordinary skill in the art. Therefore, in order to continuously produce a biological molecule from a biological characteristic consistent cell line, the motivation for combining the cell splitting and cell frozen technique would have been obvious for an ordinary skill in the art. The claimed invention drawn to a repeated discontinuous process is just a design choice based on Griffiths and Pollard's teaching and it is found no patenable weight over the prior art. Therefore, the rejection is till proper and made final.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

November 26, 2001

ALI R. SALIMI
PRIMARY EXAMINER